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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,673	07/20/2000	BRUCE PAUL DAGGY	C75087	9337

7590

07/30/2003

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EXAMINER
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HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/30/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/600,673

Applicant(s)

DAGGY ET AL.

Examiner

Anne Holleran

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 January 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 07 January 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1, 2, 4-11, and 13-18.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 3. Applicant's reply has overcome the following rejection(s): Rejection of claim 1 and 10 under 112, 1st paragraph for lack of written description, .

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1. The amendment filed Jan. 7, 2003 (Paper No. 10) is acknowledged. Claims 3 and 12 were canceled.

Claims 1, 2, 4-11 and 13-18 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections Withdrawn:***

3. The rejection of claims 1 and 10 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendment.

***Claim Rejections Maintained:***

12/7/03  
4. The rejection of claims <sup>1, 2, 4-11 and 13-18</sup> ~~1-3, 5-12 and 14-18~~ under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods where the combination of fibers includes the addition of wheat bran to cellulose, does not reasonably provide enablement for methods where the combination of fibers lacks wheat bran is maintained for the reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments have been carefully considered, but are unpersuasive. Applicant argues that the specification enables one of skill in the art to combine any of methylcellulose,

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ethylcellulose, carboxymethylcellulose or hydroxypropylmethylcellulose with either an insoluble fiber, such as wheat bran, or another soluble, fermentable fiber or make a mixture of all three types of fibers. However, the specification only contains teachings with respect to the combination of methylcellulose with wheat bran, and fails to teach whether it would be predictable to reduce the incidence of either colon cancer or breast cancer with any other combination. The prior art only teaches the benefits of combining soluble with insoluble fibers for the reduction of cancer risk. Therefore, it is not clear that one of skill in the art would know how make a method, based on the teachings of the specification, where the combination required choosing another soluble fiber to combine with any of methylcellulose, ethylcellulose, carboxymethylcellulose or hydroxypropylmethylcellulose.

5. The rejection of claims 1, 2, 5, 6, 8 and 9 under 35 U.S.C. 102(e) as being anticipated by Annison et al (U.S. Patent 5,840,860; issued 11/24/1998; effective filing date for 102(e) 9/5/1996) is maintained for the reasons of record.

Applicant's arguments have been carefully considered but are unpersuasive. The amendment to the claims fails to free the claimed methods from the teachings of Annison. Because the claims do not specify whether the derivatives comprise any of methylcellulose, ethylcellulose, carboxymethylcellulose or hydroxypropylmethylcellulose, or consist of methylcellulose, ethylcellulose, carboxymethylcellulose or hydroxypropylmethylcellulose, it appears that the methods of Annison anticipate the claimed methods.

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6. The rejection of claims 1, 2, 5, 6, 8 and 9 under 35 U.S.C. 102(b) as being anticipated by Folino et al (Folino, M. et al, J. Nutr. 125: 1521-1528, 1995) is maintained for the reasons of record.

Applicant's arguments have been carefully considered but are unpersuasive. Applicant appears to be arguing that because Folino does not explicitly teach that the purpose of feeding methyl cellulose is for the prevention of cancer that Folino fails to anticipate the claims. Folino teaches a method of administering methylcellulose to rats (see page 1522, 1<sup>st</sup> column, and Table I, page 1523). Folino teaches that the methylcellulose accounted for 1 gm of the total fiber (see Table 1). The methylcellulose appears to be administered in the form of a suspension (see notes of Table 1). Folino teaches a method comprising the same steps as those of the claimed methods, and using amounts that fall within the scope of the claims. Therefore, Folino anticipates the claimed methods. Applicant appears to be arguing that because Folino does not explicitly teach that the purpose of feeding methyl cellulose is for the prevention of cancer that Folino fails to anticipate the claims.

7. The rejection of claims 10, 11, 14, 15, 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over either Annison et al (supra) or Folino et al (supra) in view of Cohen et al (Cohen, L.A. et al., J. Natl. Cancer Inst., 88(13): 899-907, 1996; cited in the IDS) is maintained for the reasons of record.

Applicant's arguments are unpersuasive for the reasons stated above with respect to the teachings of either Annison or Folino. The teachings of Cohen are relied upon to demonstrate

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that it is known in the art that breast cancer, in addition to colorectal cancers, are treatable by the administration of dietary fibers.

8. The rejection of claims 1, 4, 10 and 13 under 35 U.S.C. 103(a) as being unpatentable over Annison et al (supra) or Folino et al (supra) in view of either Cohen et al (Cohen, L.A. et al., J. Natl. Cancer Inst., 88(13): 899-907, 1996; cited in the IDS) or Alabaster et al (Alabaster, O. et al., Cancer Letters, 75: 53-58, 1993; cited in the IDS) is maintained for the reasons of record.

Applicant's arguments are unpersuasive for the reasons stated above with respect to the teachings of either Annison or Folino. The teachings of Cohen or Alabaster are relied upon to demonstrate that it is known in the art to combine soluble and insoluble fibers, and that such combinations have a synergistic effect in colon or breast cancer risk reduction.

### *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran  
Patent Examiner  
July 25, 2003

ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

<b>Interview Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/600,673	DAGGY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne Holleran	1642	

All participants (applicant, applicant's representative, PTO personnel):

(1) Anne Holleran. (3)\_\_\_\_\_.

(2) Maureen Fitzgerald. (4)\_\_\_\_\_.

Date of Interview: on or about 7/24/2.

Type: a) ☒ Telephonic b) ☐ Video Conference  
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.  
If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: \_\_\_\_\_.

Identification of prior art discussed: \_\_\_\_\_.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Informed Maureen Fitzgerald that the amendment would be entered, but that an advisory action would be sent out, because the amendment did not obviate the grounds of rejection.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

\_\_\_\_\_  
Examiner's signature, if required



## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.